A COMPARATIVE ANALYSIS BETWEEN STENTED AND NON-STENTED TECHNIQUES IN EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY FOR UPPER URETERAL STONES

Dissertation submitted to

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

in partial fulfillment of the requirements
for the award of the degree of

M.Ch (UROLOGY) – BRANCH – IV

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY
CHENNAI

AUGUST 2011

DECLARATION

I solemnly declare that this dissertation titled **"A COMPARATIVE ANALYSIS BETWEEN STENTED AND NON-STENTED TECHNIQUES IN EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY FOR UPPER URETERAL STONES"** was prepared by me in the Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai under the guidance and supervision of **Prof.R.Jeyaraman, M.Ch .,** Professor & Head of the Department, Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai. This dissertation is submitted to the Tamil Nadu Dr.MGR Medical University, Chennai in partial fulfillment of the university requirements for the award of the degree of M.Ch. Urology.

Dr.T.R.GHURUNAATH

Place : Chennai
Date :

CERTIFICATE

This is to certify that the dissertation titled **"A COMPARATIVE ANALYSIS BETWEEN STENTED AND NON-STENTED TECHNIQUES IN EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY FOR UPPER URETERAL STONES"** submitted by **Dr.T.R.GHURUNAATH** appearing for M.Ch. (Urology) degree examination in August 2011, is a bonafide record of work done by him under my guidance and supervision in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R.Medical University, Chennai. I forward this to the Tamil Nadu Dr.M.G.R.Medical University, Chennai.

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ACKNOWLEDGEMENT

First of all, I would like to thank my patients, who subjected themselves for my dissertation work.

I whole heartedly thank **The Dean**, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai for allowing me to avail the facilities needed for my dissertation work.

I would like to express my humble gratitude to **Prof. R. Jeyaraman**, M.Ch, Professor and Head of the Department of Urology, for his expert guidance and help rendered for the conduct and completion of my dissertation work.

I would like to thankfully acknowledge **Prof.V.Kamaraj** and **Prof. RM. Meyyappan**, Professors in the Department of Urology, for their constant help in the dissertation work.

I sincerely thank the Director, Barnard Institute of radiology for his help in completing my dissertation.

I sincerely thank the Assistant Professors in the Department of Urology for their continuous inspiration and support in carrying out my dissertation.

Last, but not the least, I thank my fellow past and present postgraduates who helped me in carrying out my work and preparing this dissertation.

INDEX

INTRODUCTION

The goal of treating ureteral calculi is to achieve complete stone clearance with minimal morbidity for the patient. The factors that must be considered when recommending treatment to patients with ureteric calculi may be grouped into three broad categories: stone-related factors (location, size, composition, duration, and degree of obstruction), clinical factors (the patient's tolerance of symptomatic events, the patient's expectation, associated infection, solitary kidney, abnormal ureteric anatomy, and technical factors (equipment available for treatment, costs). These factors may be thought of as treatment modifiers. Nevertheless, several surgical options are available for proximal ureteral calculi.

Advances in ureteroscope design, newer methods of intracorporeal stone fragmentation, laparoscopic techniques and ongoing developments in extracorporeal shock wave lithotripsy have resulted in changes with regard to the use of treatment modalities for ureteral stones.[1]

Extracorporeal shock wave lithotripsy (ESWL) is the least invasive treatment for calculi of the upper urinary tract and it is recommended as first line therapy.[2] However, ESWL has a variable success rate for large upper ureteral calculi.[3,4]

Development of the small flexible ureterorenoscope combined with advancements in intracorporeal lithotriptors have increased the success rate for managing upper ureteral calculi. However, flexible ureteroscopes are expensive and technique dependent. Moreover, the current trend in surgery is toward minimally invasive procedures.

The use of stents for extracorporeal shock wave lithotripsy in certain renal and ureteral stones remains controversial. The major benefit of stents is to prevent complications associated with ureteral obstruction as stone fragments pass down the ureter. Conversely, the main drawbacks associated with stents are irritative symptoms and bladder discomfort in addition to inherent risks of stent migration, vesicoureteral reflux and stent encrustation.[5]

The effect of ureteric stent on the outcome of ESWL continues to pose a dilemma, with no clear published recommendations. Though the use of stents is unavoidable in some cases (e.g. obstruction, sepsis), ureteric stents have not always previously been identified as a factor associated with failure of ESWL, and some authors have claimed that it does not affect the treatment outcome.[6,7]

Success of ESWL has been correlated with radio density of the stone on the plain X-ray KUB. Overall accuracy of predicting calculi composition from plain radiographs was reported to be only 39% which at present is insufficient for clinical use.

The emergence of Non Contrast Computed Tomography scan (NCCT) in the assessment of flank pain and the subsequent availability of the attenuation coefficient measurement has made several authors comparing attenuation and stone composition in vitro. These studies have determined that stone compositions can be predicted on the basis of the attenuation value determined by NCCT.

The density of stone measured by NCCT, stone Hounsfield Unit (HU) varies with stone composition and determines the fragility of a calculus which ultimately governs the clinical outcome in ESWL. NCCT because of its easy availability, excellent sensitivity and very high resolution capability is a good modality for the measurement of stone density.

AIM

The aim of this study is

1) To identify the effect of the presence of a ureteric stent on the outcome of extracorporeal shockwave lithotripsy (ESWL), by comparing patients with ureteric stones with matched-pair analysis.

2) To find out complications of extracorporeal shock wave lithotripsy during the management of upper ureteric calculus

REVIEW OF LITERATURE

THE EVOLUTION OF MACHINE DESIGN

Shock wave lithotripsy (SWL) was introduced in the 1980s for the treatment of urinary stones and earned near-instantaneous acceptance as a first line treatment option.

The word Lithotripter is Greek origin and means stone crusher. Lithotripters have evolved from many years of research into physics of flight. Researchers discovered that raindrops striking an air craft during supersonic flight created shockwaves that had disintegrating effects on solid materials. Refinements of these findings led to the invention of the Lithotripter as a means for treating urinary calculi.

In February 1980 Dr.Christian Chaussay**,** at the University of Munich first used electrically generated focused shockwaves to fragment stones within a human kidney.[8] The first experimental treatment began the era of ESWL. The first Lithotripter model HM 1 soon replaced by HM 2 in 1982 and in 1984 by Model HM 3. Each new generation reflects progression of technology and a growing sophistication. Further modification of the generation is the consolidation of fluoroscopic screens and the lithotripsy control into a convenient, efficient and user friendly console.

Shockwave lithotripsy technology has advanced rapidly in terms of shock wave generation, focusing, patient coupling and stone localization making it the most widely used treatment for renal and ureteric calculi. Over the years, lithotripsy has undergone several waves of technological advancement, but with little change in the fundamentals of shock wave generation and delivery.

Traditionally lithotriptors have been categorized as first-, second- or third generation (an unfortunate and confusing classification system) devices. The Dornier HM3 is the first generation lithotriptor. It features an electro hydraulic source mounted at the floor of a large water bath in which the patient is placed, and which provides for optimal coupling to deliver SW energy to the body. Stone localization is via biplanar fluoroscopic imaging. Depending upon the case at hand, local sedation, regional, or general anesthesia is applied. Second generation lithotriptors feature an electrohydraulic, electromagnetic or piezoelectric shock wave source (see below). Coupling is provided by a water cushion or partial water bath. The machines are further equipped with either ultrasonic or fluoroscopic imaging and have lessened anesthesia requirements. Limited multifunctional and/or multidisciplinary use is possible. These devices generate peak pressures similar to or lower than the HM3 but with smaller focal zones.

Third generation lithotriptors are equipped with a combined targeting system consisting of fluoroscopy and ultrasound to be used alternately or, in the ideal situation, simultaneously. They also have lessened anesthesia requirements and the integration of both fluoroscopy and ultrasound in an endourologic treatment table facilitate multi-functional and multidisciplinary use. These devices typically have higher peak pressures and smaller focal zones than the HM3.

THE PHYSICS OF CLINICAL LITHOTRIPSY

Three shock wave generating principles have been used in clinical lithotriptors..

a) Electrohydraulic lithotriptors (EHL-SWLs)

An electrohydraulic shock wave source consists of a spark plug placed underwater with a gap of approximately 1 mm between the two electrode tips. A capacitor is charged to a voltage between 12 and 30 kV and then abruptly discharged causing the explosive formation of an underwater plasma channel in the gap. The resulting rapid evaporation of the water surrounding the electrode tips releases a spherical (unfocused) shock wave. The spark plug is positioned at the first focus (F1) of an ellipsoidal bowl and the spherical shock wave reflects from the surface of the ellipsoidal bowl and converges (focuses) at the second focus (F2).[9]

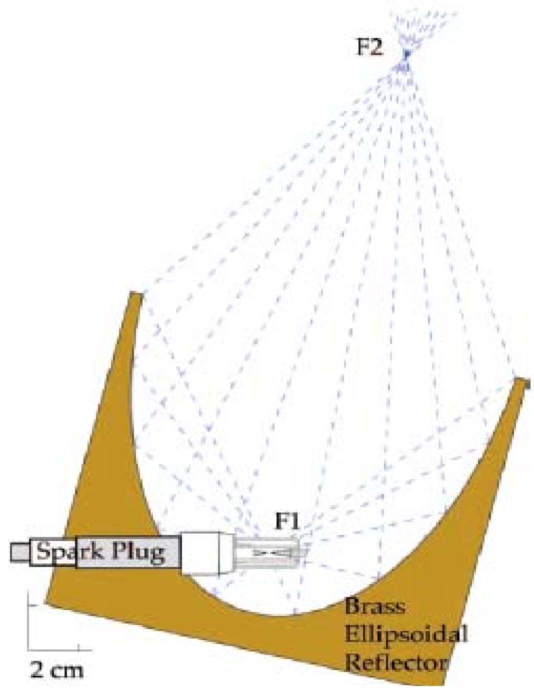

Fig. 1. Electrohydraulic lithotriptor

The process causes erosion of the electrode tips leading to irregularities in the resulting spark and the shock wave originating from it. The erosion of the electrode tips thus limits the lifetime of the spark plug to several thousand shocks per spark plug. The Dornier HM3 had a complete water bath, which provided optimal coupling but subsequent EHL-SWLs have the shock wave source mounted in a sealed therapy head which is coupled to the body using gel or oil.

b) Electromagnetic lithotriptors (EMLs)

Electromagnetic shock wave generators are available in several geometries. In one case an electric coil is formed on a flat surface and a conductive membrane placed on top. A capacitor is then discharged through the coil which produces a magnetic field that repels the membrane resulting in the generation of a plane (unfocused wave) which is focused with an acoustic lens. In another geometry the coil is wrapped around a cylinder (about the size of a soup can) and the wave spreads out cylindrically (unfocused) from the coil.

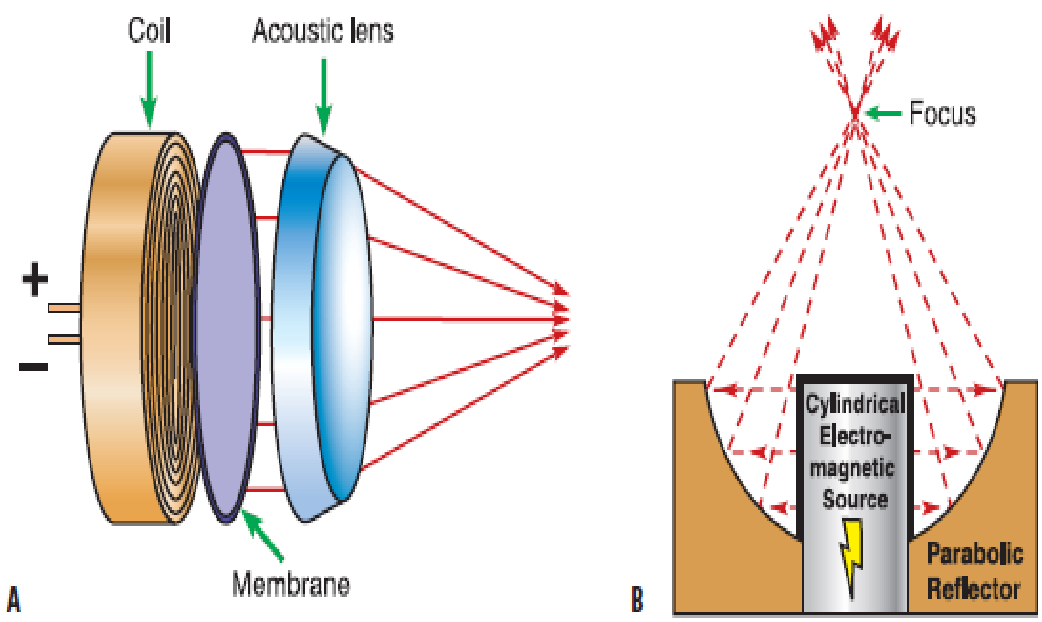

Fig. 2. Focusing mechanisms employed in electromagnetic lithotriptors A, Focused by an acoustic lens. B, Focused by a parabolic reflector

The coil is placed within a parabolic reflector which acts to focus the cylindrical wave. In a third approach the coil is formed on the inner surface of a spherical cap. When the coil is excited the wave generated has the same curvature as the spherical cap and therefore starts off as a focused wave propagating toward the centre of the radius of curvature of the spherical surface.[10] In all cases the initial wave is not a true shock wave but as it propagates towards the focus it evolves into a shock wave.

All electromagnetic shock wave sources are in a sealed therapy head, which is coupled to the body using gel or oil, except for the Storz devices which couple the sealed therapy head via a small, shallow water bath. Electromagnetic shock wave sources are more consistent and reproducible than EHLSWL spark-gap sources and have a lifetime of about two million SW's.

c) Piezoelectric lithotriptors (PELs)

A piezoelectric shockwave generator consists of a concave spherical cap lined on the inner surface with piezoceramic elements—typically hundreds or thousands are employed. Piezoceramic elements rapidly change shape in response to an electric current.

A capacitor is discharged through these elements, which because of the geometry of the sphere, produces an acoustic wave with a spherically converging wave front. The pressure wave focuses at the centre of the sphere. As with the EMLs the wave does not start as a shock wave but rather develops into a shock wave due to non-linear propagation

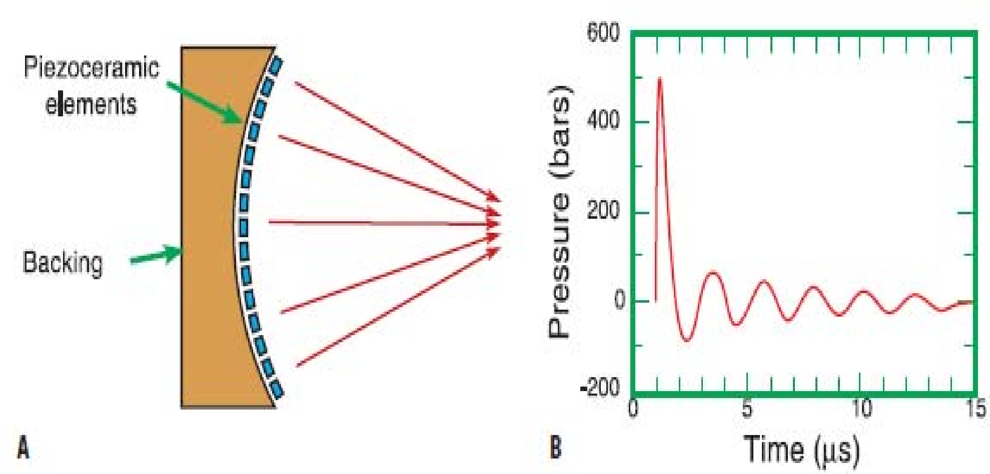

Fig. 3: (A) Fundamental principles for a piezoelectric lithotriptor. (B) Typical waveform measured at the focus of a piezoelectric lithotriptor

Typically PELs are mounted in the therapy head like other SW sources. One notable exception was the original Wolf Piezolith which was equipped with a partial water bath bringing the patient in direct contact with the water. Although piezoelectric shockwave sources develop high focal pressures this technology generally is considered to be less effective than other devices, as the clinical data shows a high re-treatment rate.[11]

ASSESSMENT OF LITHOTRIPTOR PERFORMANCE

Owing to the wide variety of makes and models of lithotriptors, with different generators and energies, and subtle variations in overall patient care among investigators, it becomes difficult to make comparisons between series of reported data. For example, for a given stone-free rate, one machine may require multiple re-treatments or subsequent stent placements. Denstedt and colleagues [12] described the use of an “efficiency quotient” to take such factors into account as follows: efficiency quotient (EQ) = % stone-free divided by (100 + % re-treated + % auxiliary procedures). Therefore, a lithotriptor with an 85% stone-free rate, 10% re-treatment rate, and 15% rate of additional procedures would have an efficiency quotient of 0.68, whereas another machine which also has an 85% stone-free rate but with no re-treatments or ancillary procedures would have an EQ of 0.85. It is evident that despite the same stone-free rates, the two machines are not equally “efficient.”

This methodology is also useful in comparing results of SWL to other modalities, such as ureteroscopy or percutaneous nephrolithotomy. Unfortunately, only a small fraction of the current peer-reviewed literature reported EQs, and stone-free rates were the primary measure of success. Overall results of SWL for solitary nonstaghorn renal calculi in any location vary from EQs of 0.45 to 0.82 for electrohydraulic lithotriptors and 0.42–0.67 for electromagnetic lithotriptors.[13,14]

SHOCK WAVE COUPLING

Shock waves can be coupled effectively into body by degassed water which has matched acoustic impedance to soft tissues. Current Lithotripter use enclosed water cushion with a coupling medium of ultrasound gel instead of 1000 L water bath. Shock wave attenuation through the membrane of water cushion amounts to 20% loss of energy.

STONE LOCALIZATION

Stone localization during lithotripsy is accomplished with either fluoroscopy (or) ultrasonography.

FLUOROSCOPY

Advantages

- ❖ In situ treatment of ureteral stones in all parts of the ureter
- ❖ Shorter learning curve
- ❖ Automatic positioning mode available on some systems

Disadvantages

- ❖ No direct targeting of radiolucent stones
- ❖ Small stones sometimes difficult to locate
- ❖ No real-time image
- ❖ Exposure to radiation

ULTRASOUND

Advantages

- ❖ Easy targeting of radiolucent stones
- ❖ Easier targeting of smaller renal stones
- ❖ Real-time image: easier, faster focusing
- ❖ No exposure to radiation

Disadvantages

- ❖ In situ treatment of ureteral stones is possible only for very proximal and very distal ureteral calculi
- ❖ Longer learning curve
- ❖ Poor imaging with obese patients

PHYSICAL PROPERTIES OF CALCULI AND TISSUE

Knowledge of acoustic and mechanical properties of renal, ureteric calculi and tissue is important to understand shockwave – stone tissue interaction and the mechanisms of stone fragmentation and tissue injury during ESWL. Acoustic properties determine the characteristics of shock wave propagation inside the stone and tissue materials as well as the wave transmission and reflection, at the stone tissue boundary. Mechanical properties dictate the response of the stone and tissue materials to shock wave loadings. Acoustic and mechanical properties of calculi depend primarily on the composition of stone.

Acoustic properties are density, wave speed and acoustic impedance. Longitudinal wave propagation (compression) characterized by parallel movements of material particles along the wave path. Transverse (Shear) wave propagation material particles move perpendicularly to wave path.

Calcium oxalate monohydrate and cystine stones have higher acoustic impedance. Stones with higher acoustic impedance would produce a stronger reflection of the shock wave at the anterior surface of stone resulting in less of the shock wave energy being transmitted into the stone to cause fragmentation.

COMPOSITION AND STRUCTURAL FEATURES OF CALCULI

The constituents of renal calculi are crystalline (95%) and non crystalline matrix materials (protein, cellular debris and organic materials).Major crystalline components are calcium oxalate (monohydrate and dihydrate), phosphates (hydroxyapatite, carbonate apatite - struvite) uric acid, cystine and xanthine. Calculi appear in wide range of shapes, sizes, colors and textures.

MECHANICAL PROPERTIES OF CALCULI

Dynamic elastic properties of calculi depends upon resistance of stone material to elongation (or) shortening, shear deformation and volume change. Most renal calculi are brittle while cystine stones are ductile (more energy is needed to produce fracture) so they are most difficult to fragment during SWL.

MECHANISMS OF VARYING STONE FRAGILITY

Stone fragility determines the response of a ureteric calculus to SWL. The response varies with composition, size and structural features of stone.

It has been reported that stone with homogenous structure are less fragile than stones with heterogeneous structure. Elastic module determine a stones resistance to shock wave induced deformation, hardness determine a stone's resistance to cavitation, microjet impact and fracture toughness determines a stone's resistance to spalling damage and crack propagation. Calcium oxalate monohydrate and brushite stones are less fragile than magnesium ammonium phosphates and carboxy apatite stones because calcium oxalate monohydrate and brushite stones are stiffer, harder and more resistant to fracture. Based on the above factors, cystine stones are most ESWL resistant, next are brushite, and calcium oxalate monohydrate.

HOW SHOCK WAVES BREAK STONES

Numerous mechanisms by which shock waves may fragment stones have been described in the literature. Here, we give a synopsis of some of the most likely mechanisms.

Spall Fracture:- *Spallation* occurs after the shock wave enters the stone and subsequently reflects from the rear of the stone . The stone/urine interface inverts the large positive pressure pulse, resulting in a large tensile stress. This stress is added to the tensile stress of the still-incoming negative pressure tail, resulting in a very large tensile stress near the back wall.[15,16] Most solids are much weaker in tension than in compression, and so the large tensile stress near the rear of the stone can be expected to make the material fail.

Shear Stress: *Shear* stresses will be generated by a combination of both shear waves and compressive waves that develop as the shock wave passes into the stone.[17] Many materials are weak in shear, particularly like kidney stones if they consist of layers, as the bonding strength of the matrix between layers often has a low ultimate shear stress. Furthermore, the organic binder of kidney stones is much softer than the crystalline phase, and as the shock front passes through the stone, it will induce very large shear stresses at the binder/crystal interfaces, which likely contribute to the fracture of the kidney stone. Shear waves in the stone can also result in large tensile stresses that exceed the tensile stress induced by spallation.

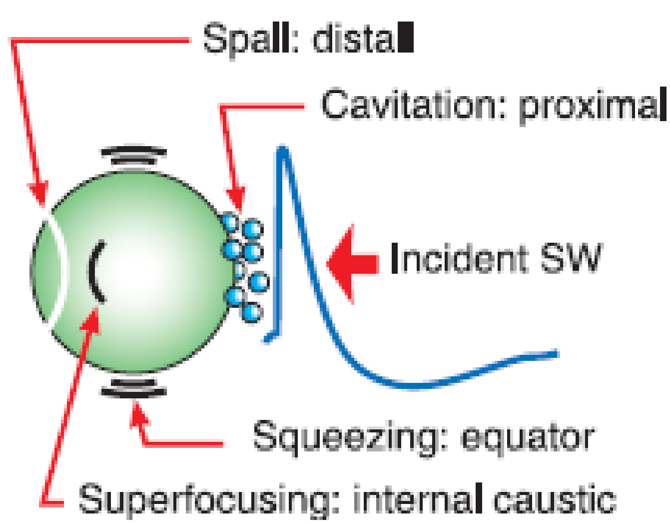

Fig-4: Schematic showing regions where different stone fracture mechanisms will act.

Superfocusing: Superfocusing is the amplification of stresses inside the stone due to the geometry of the stone. The shock wave that is reflected at the distal surface of the stone can be focused either by refraction (associated with the high sound-speed and geometry of the stone) or by diffraction from the corners of the stone. It has been shown that these reflected waves can be focused to caustics (regions of high stress) in the interior of the stone and that this can lead to failure. The regions of high stress (both tensile and shear) can be determined from the geometry of the stone and its elastic properties (eg, density, longitudinal wave speed, and shear wave speed).

Squeezing: Squeezing/splitting occurs because of the difference in sound speed between the stone (greater than 2,500 m/s) and the surrounding fluid (≈1,500 m/s). The shock wave inside the stone "runs away" from the shock wave propagating through the fluid outside of the stone. The shock wave that propagates in the fluid outside the stone results in a circumferential force on the stone (known as a hoop stress). This results in a maximum tensile stress at proximal and distal ends of the stone and leads to an axial "splitting" failure. It has been theorized that squeezing should be enhanced when the entire stone falls within the diameter of the focal zone, and a lithotriptor based on this principal has recently been built and described in the literature.

Cavitation: *Cavitation* refers to small bubbles (or cavities) that grow in the urine surrounding the stone in response to the large negative pressure tail of the acoustic pulse. When a cavitation bubble collapses near a solid surface (eg, a kidney stone) a microjet of fluid is formed that pierces the bubble and impacts the surface with speeds upwards of 100 m/s. This jet likely plays a role in cavitation-induced damage to kidney stones.[18] The collapse of the cavitation bubble also results in the emissions of secondary shock waves that are radiated into the bubble. These secondary shock waves have an amplitude comparable to that of the focused shock wave. In vitro experiments where cavitation is suppressed show significant reduction in stone fragmentation. Cavitation is principally a surface-acting mechanism, and experiments indicate that it acts most strongly on the proximal (shock wave incident) surface of the stone. It has also been suggested that the stresses imparted by cavitation can act by a spall mechanism.Recent work has recognized that the cavitation generated by lithotriptors acts as a cluster of bubbles rather than individual bubbles, and that the coherent collapse of the cluster may enhance the destructive power of cavitation.[19]

Fatigue: *Fatigue* is a process that may occur anywhere in the stone. Its hallmark is the progressive development of cracks. The cracks are nucleated at sites of small imperfections that occur in almost all materials - these nucleation sites will be present in all kidney stones. The imperfections are sites of “stress concentrations” which, when a shock wave passes, can lead to local stresses far in excess of the average stress induced by the shock wave. With the impact of repetitive shock waves, the imperfections frow into microcracks. With subsequent shock waves, the microcracks grow into macrocracks, and eventually produce cracks large enough to induce failure. The cracks can be grown either by large tensile stresses or by large shear stresses. Therefore, fatigue will be enhanced wherever regions of high stress coincide with weak points in the stone. This means that there could be a synergistic effect between fatigue and some of the other mechanisms that result in localized regions of high tensile or shear stress. There are two pieces of evidence that strongly support the argument that stone comminution is a fatigue process. First, the internal structure of stones has been shown to affect how they fragment in lithotripsy.[20] Second, normally more than 1,000 shock waves are required to progressively fragment stones into sufficiently small pieces; the use of multiple stress cycles to fracture a material is a classic hallmark of fatigue.

CHARACTERISTICS OF A LITHOTRIPTOR SHOCK WAVE

A typical shock wave measured at the focus of a lithotriptor is shown in Fig.5.

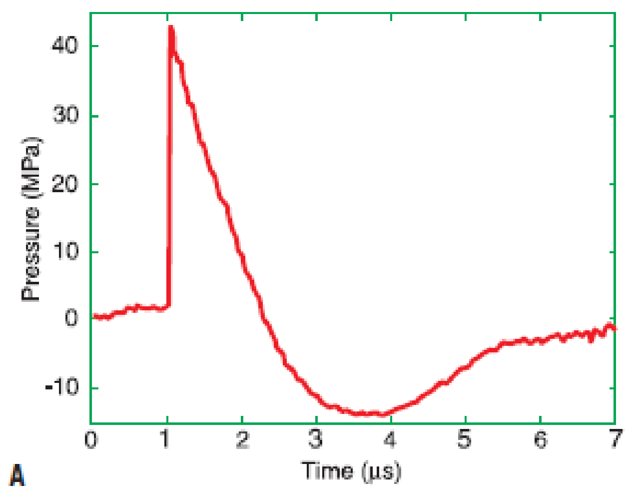

Fig 5. A pressure waveform measured at the focus of an electrohydraulic lithotriptor

The wave is a short pulse of about 5 µs duration. Shock waves composed of positive compressive waves and negative tensile waves. Initial short and steep compressive front with pressures of about 40 MPa that is followed by a longer, lower amplitude negative (tensile) pressure of 10 MPa, with the entire pulse lasting for duration of 4 µs. Note that the ratio of the positive to negative peak pressures is approximately 5. Pressure measurements near the focal region of a Dornier unmodified HM3 indicate a 6-dB beam, of a width of approximately 15 mm. Since most of renal and ureteric stones are also generally of this dimension, the wave front incident on the stone can be considered a plane wave.

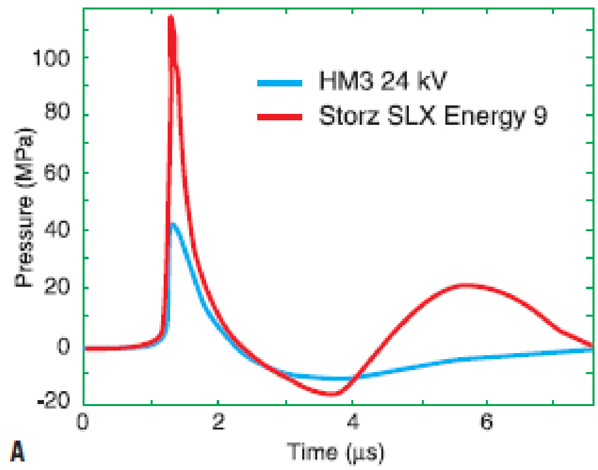

Fig 6. Focal waveforms measured in the electrohydraulic lithotripter (Dornier HM3) and an electromagnetic lithotripter (Storz SLX Energy 9).

In Fig 6 we compare waveforms measured in an electrohydraulic lithotripter (Dornier HM3) and an electromagnetic lithotripter (Storz SLX Energy 9). It shows that the features of waveform are similar regardless of the type of lithotriptor, but there are considerable differences in the amplitude and spatial extent of the acoustic output. . It is likely that the amplitude and size of the focal zone of different lithotriptors affects their performance.

Roentgenography has played a major role in the diagnosis and management of calculus disease. Various researchers have attempted to predict the stone composition by different methods.

In 1996 ***Dretler and Koff*** [21] further analyzed radiographic patterns of calcium oxalate dihydrate and monohydrate stones. Smooth edge, denser than bone, homogenous are pure calcium oxalate monohydrate stones. Radial striations and superimposed stippling pattern in calcium oxalate dihydrate stones. This study is the first proof that radiographic morphology can be related to ESWL stone free rate.

EXTRACORPOREAL SHOCK WAVE IN THE TREATMENT OF URETERIC CALCULI

Chaussy and his colleagues initially treated ureteric stones insitu and reported < 50% success rate. Most of the stones had been disintegrated, but the pieces were held together by edematous mucosa. This was seen in patients with stones impacted. This observation led Chaussy to use an ureteric catheter or an ureteroscope to push the ureteric stone into the renal collecting system. The success of this treatment was 75 - 95%.

ASSESSMENT OF FRAGMENTATION

One of the troublesome aspect of ESWL is determining the adequacy of fragmentation. One of the best indications is dispersion of sand, but this can occur only if the stone is located in a large cavity such as renal pelvis. Barr et al 1990 noted that both Calyceal and Ureteric stones may be fragmented satisfactorily, but radiographic appearance may appear unchanged. Hence even if the 24-hour post treatment plain radiograph shows no definite pulverization the patient should be followed for a couple of weeks before considering retreatment.

IMPACTED URETERIC STONES

An impacted stone may be defined as a stone that cannot be bypassed by a wire or catheter or a stone that remains at the same site in the ureter for more than 2 months. The presumed action of shockwaves on a stone is the creation of interacting compressive and tensile forces at fluid stone interfaces. Stone fragment is torn off in layers. Green and Lytton, 1985 [22] & Farsi et al [23], 1994 in their study noticed that impacted stones are often more resistant to fragmentation by ESWL. One explanation for this observation is expansion space theory the initial shock waves remove an outer layer of stone material, but the surrounding ureteric walls do not allow these particles to fall away. The new fluid –stone interfaces interfere with the transmission of next series of shock waves to the core of the stone, thereby preventing complete fragmentation. This situation can be remedied by push back to kidney with a ureteric catheter or ureteroscope, by bypassing the stone with a ureteric catheter to provide an artificial expansion space, or by irrigating the stone during insitu ESWL using saline to flush the particles away from the solid core. The only disadvantage to ureteric irrigation is that renal pelvic pressure may raise enough to result in forniceal tear and extravasation.

Although these reports suggest that ureteroscopy may be the optimal approach to the impacted ureteric stone, some urologists still favor SWL as the initial approach for stones smaller than 1 cm in the ureter. However, ureteroscopy may be the treatment of choice for patients whose SWL treatment failed, for patients with cystinuria, for patients with distal obstruction, for patients with impacted stones, for obese patients, for patients with bleeding diathesis, and when SWL is not readily available.

Under the sage leadership of the late Dr. Joseph W. Segura, the AUA Practice Guidelines Committee suggested to both the AUA and the EAU that they join efforts in developing the first set of internationally endorsed guidelines focusing on the changes introduced in ureteral stone management over the last decade.

This joint ***EAU/AUA Nephrolithiasis Guideline Panel – 2007***[24] performed a systematic review of the English language literature published since 1997 and a comprehensively analyzed outcomes data from the identified studies. Based on their findings, the Panel concluded that when removal becomes necessary, SWL and ureteroscopy (URS) remain the two primary treatment modalities for the management of symptomatic ureteral calculi. Other treatments were reviewed, including medical expulsive therapy (MET) to facilitate spontaneous stone passage, percutaneous antegrade ureteroscopy, and laparoscopic and open surgical ureterolithotomy.

Procedures per patient were counted in three totals: primary procedures, secondary procedures, and adjunctive procedures. Primary procedures were all consecutive procedures of the same type aimed at removing the stone. Secondary procedures were all other procedures used to remove the stone. Adjunctive procedures were defined as additional procedures that do not involve active stone removal.

Analyses were performed for the following patient groups:

1. Proximal stones ≤10 mm
2. Proximal stones >10 mm
3. Proximal stones regardless of size

For Ureteral Stones <10 mm:

Standard: Patients should be followed with periodic imaging studies to monitor stone position and to assess for hydronephrosis. Stone removal is indicated in the presence of persistent obstruction, failure of stone progression, or in the presence of increasing or unremitting colic.

For Ureteral Stones >10 mm:

Although patients with ureteral stones >10 mm could be observed or treated withMET, in most cases such stones will require surgical treatment.

Standard: A patient must be informed about the existing active treatment modalities, including the relative benefits and risks associated with each modality.

Recommendation: For patients requiring stone removal, both SWL and URS are acceptable first-line treatments. Routine stenting is not recommended as part of SWL.

The current meta-analysis analyzed SWL stone-free results for three locations in the ureter (proximal, mid, distal). The SWL stone-free results are 82% in the proximal ureter (41 studies, 6,428 patients), 73% in the mid ureter (31 studies, 1,607 patients), and 74% in the distal ureter (50 studies, 6,981 patients). The results in the 1997 guideline, which divided the ureter into proximal and distal only, reported SWL stone-free results of 83% and 85%, respectively. The Confidence Intervals for the distal ureter do not overlap and indicate a statistically significant worsening of results in the distal ureter from the earlier results. No change is shown for the proximal ureter. The cause of this difference is not clear. Additional procedures also were infrequently necessary (0.62 procedures per patient for proximal ureteral stones, 0.52 for mid-ureteral stones, and 0.37 for distal ureteral stones).

Serious complications were again infrequent. As expected, stone-free rates were lower and the number of procedures necessary were higher for ureteral stones >10 mm in diameter managed with SWL.

The newer generation lithotriptors with higher peak pressures and smaller focal zones should, in theory, be ideal for the treatment of stones in the ureter but instead have not been associated with an improvement in stone-free rates or a reduction in the number of procedures needed when this treatment approach is chosen.

SUCCES OF ESWL

In a large series by Taku Abe et al [25] with a total of 2844 patients (3061 renal units) after follow up period of 3 months defined stone free as having no stone material radiographically or ultrasonographically, and success was defined as being stone free or having residual fragments ≤ 4 mm in diameter. They also defined recurrence of calculi as radiologic or ultrasonographic evidence of an upper urinary tract stone on the ipsilateral side.

CONTRAINDICATIONS TO ESWL

Absolute

- Pregnancy
- Uncorrected bleeding disorder
- Active sepsis or untreated urinary tract infection
- Untreated obstruction distal to the stone

Relative

Stone Factors:

- Size - large stones > 2cm maximum diameter or staghorn
- Location: lower calyceal, especially if > 1cm
- Number: more than 1, especially if large or in different locations

- Composition: hard stones such as calcium oxalate monohydrate, calcium phosphate or cystine
- Previous failed SWL for same stone

Patient Factors

- Obesity
- Uncontrolled hypertension
- Proximate aneurysms
- Cardiac pacemakers
- Significant cardiopulmonary disease
- Inability to be properly positioned (i.e. Orthopedic deformity)
- Severe gastrointestinal disease
- Impaired cognitive ability

COMPLICATIONS

The ultimate goal of ESWL is to fragment renal and ureteric calculi as effectively as possible with minimizing the potential injury to surrounding tissues. Most SWL complications are minor and self-limiting, such as transient hematuria, pain, nausea and vomiting, there are also life threatening case reports described in the literature.[26]

Steinstrasse

Post-SWL urinary obstruction owing to ureteral impaction of fragments is referred to as steinstrasse, or “street of stone,” which connotes the classic radiographic findings. Steinstrasse occurs in up to 15% of radiography obtained within 48 h of SWL, and is found most commonly in the distal one-third of the ureter. Up to 50% of patients found to have steinstrasse require intervention, which most often involves either placement of a percutaneous nephrostomy tube or repeat ESWL.[27]

Coptcoat and associates classified Steinstrasse into three subtypes.[28] Type I consists of a column of dust or gravel, and is the most common type. Type II is caused by an impacted large “lead fragment” with dust or gravel stacked behind it. Type III refers to a column of large fragments.

The initial management of symptomatic Steinstrasse consists of hydration and analgesia. Persistent obstruction requires the placement of a percutaneous nephrostomy tube. Middle or upper pole access is preferred in case an antegrade approach is needed. Ureteral stent placement can be difficult and dangerous because the ureter is acutely inflamed and often tightly impacted with fragments. Subsequent intervention for failed conservative management is tailored to the type of steinstrasse. Most type I steinstrasse will pass with nephrostomy placement alone, which relieves the acute obstruction and, in turn, restores ureteral peristalsis. Type II steinstrasse may need repeat SWL or ureteroscopic lithotripsy to the lead fragment. Type III steinstrasse will need definitive management with SWL, ureteroscopy, or a percutaneous approach, depending on the location and stone burden. Open surgery has been required in 2–4% of patients with symptomatic steinstrasse. Preoperative placement of a ureteral stent may reduce the incidence of steinstrasse.

In 400 patients randomized to stent or none before SWL for 1.5–3.5-cm renal calculi, the incidence of steinstrasse was 6% and 12%, respectively.[29] However, according to the authors, stenting did not seem to alter the presentation, treatment, or outcome of steinstrasse. As an adjunct to endoscopic management of severe steinstrasse, ureteral meatotomy has been employed by the authors. Using a wide "cutting" incision of the ureteral orifice and judicious "spot" fulguration as needed, this technique provides improved ureteral drainage and easier ureteral access, and is particularly useful when multiple procedures for steinstrasse are anticipated. Resultant vesicoureteral reflux has not been found to be an issue in our experience.

In a series of 1,130 ureteral stone SWL treatments Coz et al reported no complications. [30] In a series of 442 patients Park et al reported that 3 had steinstrasse, 10 had fever and 10.5% experienced pain.[31] In a review of complications in SWL series comprising 100 or more procedures published since 1998 with a total of 1,683 cases showed that the overall incidence of major and minor complications was 0.36% and 5.8%, respectively. [32] These results suggest that complications occur more in patients in whom SWL fails. These patients typically have larger stones and multiple treatment sessions.

In a randomized outcomes trial of ureteral stents for extracorporeal shock wave lithotripsy of solitary kidney or proximal ureteral stones by Chandhoke P S et al [33] concluded that size 4.7Fr stents may be preferable over 7Fr stents when used in conjunction with shock wave lithotripsy.

George haleblian et al [34] in a systematic review ureteral stenting and urinary stone management concluded that stenting is not mandatory after uncomplicated simple ureteroscopy and shock wave lithotripsy. Patients with stents seem to have significantly more bladder and lower urinary tract symptoms than those in whom stents are not placed. However, there is a subgroup of patients who likely benefit from stenting following a procedure because of the increased risk of complications. The ideal ureteral stent biomaterial has yet to be discovered and an area of promising development is the drug eluting stent to prevent infection and encrustation.

MATERIALS AND METHODS

PERIOD OF STUDY

January 2009 – April 2011

STUDY DESIGN

Prospective study

SOURCE OF PATIENTS

The study was conducted in the Department of Urology, Rajiv Gandhi Government General Hospital and Madras Medical College, Chennai from the patients who reported for the management of upper ureteric calculus.

Guidelines of the ethics committee were followed. All the patients were informed about the study and a consent form was signed by them. A previously designed proforma was filled to recorded data.

METHOD OF STUDY

All the patients were explained about the available modalities of treatments and their complications in the management of upper ureteric calculus – Medical Expulsion Therapy, Ureteroscopy with Intracorporeal Lithotripsy, Extracorporeal Lithotripsy, Percutaneous Nephrolithotomy and Open Surgery.

PATIENT EVALUATION

A detailed history and a clinical examination was performed followed by baseline investigations including complete blood count, blood sugar, urea, serum creatinine, urine routine including culture and sensitivity were done in all patients. A plain X ray KUB and Ultrasound were done in all patients. Either Intravenous Urogram or Contrast Enhanced CT KUB was done as a functional study.

Stone size measurements taken in the study – largest dimension in plain X ray KUB and Ultrasound.

INCLUSION CRITERIA

1) Patients with unilateral upper ureteric calculus willing for extracorporeal shockwave lithotripsy.

2) Patients with normal renal parameters.

3) No previous treatments for the same ureteric calculus.

4) No anatomical anomalies in the urinary tract.

EXCLUTION CRITERIA

1) Not willing for ESWL

2) Bilateral ureteric calculi

3) Coagulation disorder/patients on anticoagulation drugs

4) Pregnancy

5) Sepsis

6) End stage renal disease

Three hundered patients selected were divided into two equal groups of 150 each during the period, January 2009 to April 2011. The patients were divided into two groups, Group A and Group B. They were offered two folded pieces of paper bearing letter A or B and were requested to take one of these. Those who picked A were included in group A and selected for ESWL with DJ stent and those who picked B included in group B were given in situ ESWL without DJ stent.

In the patients selected for DJ placement a prophylactic injection of gentamycin 80 mg IM was given one hour prior to the insertation DJ stent and then a 5 Fr 26 cm DJ stent was placed under local, regional or general anaesthesia before ESWL.

PATIENT PREPARATION & TECNIQUE OF ESWL

Bowel preparation with anti flatulent & laxatives a day before procedure.

POSITION OF PATIENT

Supine

ANAESTHESIA/ANALGESIA

Inj.Pentazocine 30 mgs and Inj.Promethazine hcl 25 mgs intramuscularly 30 minutes before the procedure.

TECNIQUE OF ESWL

All treatments were done with ***Donier Compact Delta*** II (Electromagnetic Generator) device as outpatient procedure.

Stone was localized with fluoroscopy.

2500 shockwaves were given. The energy intensity was kept between 4 and 5 and the shockwave rate was 60 per minute.

POST PROCEDURE

After each session of treatment patients were observed for 2-3 hours and allowed to go home. Patients were explained about the post treatment hematuria, dysuria and passage of stone fragment in the urine. Patients advised to maintain adequate oral fluids.

FOLLOWUP

Patients were followed up at 15 days, 30 days, 60 days and in 90 days or whenever patients had unusual urinary complaints after the procedure.

Failure was defined as the presence of fragments of any size in the follow-up film 3 months after the final ESWL session. [35]

Although history, physical examination, Ultrasound KUB, X ray KUB was done during all visits, a plain X-ray film was used as the standard method to identify residual fragments. The treatment protocol included a second session of ESWL and if necessary a third session of ESWL. The patients follow up was terminated if the patient cleared the stone with ESWL or a secondary treatment was selected for the failure of ESWL.

For each group, hematuria, fever, steinstrasse, ureteric colic requiring hospital admissions, lower urinary tract symptoms, stone clearance, number of ESWL sessions, and secondary procedures were recorded. The DJ stent was removed when the stone disappeared or at three months whichever is earlier.

STUDY ANALYSIS

Data was analyzed using SPSS (V: 17) software.

OBSERVATION & RESULTS

The study comprised of 300 patients of upper ureteric calculus divided into two groups, 150 patients in each group. Group A comprised of pre ESWL stented patients and group B were non-stented patients who had satisfied the inclusion and exclusion criteria.

AGE DISTRIBUTION

Age of the patients ranged from 17-70 yrs and most patients were in 21-40 years of age.

Table-1: Showing age distribution in both age groups

AGE (YRS)	*NO. OF PATIENTS*	
	STENTED	*NON-STENTED*
<20	2	4
21-40	94	96
41-60	41	47
>60	13	3
TOTAL	150	150

P=0.06 not significant

SEX DISTRIBUTION

There were 114 male and 36 female patients in group A and 118 males and 32 females in group B our study.

Table 2. Showing sex distribution in both age groups

	NO. OF PATIENTS		***TOTAL***
	STENTED	***NON-STENTED***	
MALE	114	118	232 (77.3%)
FEMALE	36	32	68 (22.6%)
TOTAL	150	150	300

P=0.581 not significant

SIDE DISTRIBUTION

Left side stones predominated over right sided stones in both group A and B.

Table-4: Showing side distribution in both age groups

SIDE	***NO. OF PATIENTS***		***TOTAL***
	STENTED	***NON-STENTED***	
RIGHT	71	73	144 (48 %)
LEFT	79	77	156 (52%)

P=0.817 not significant

STONE SIZE DISTRIBUTION

In our study size of the upper ureteric calculus range from 8mm-19mm. Both group A and Group B were matched to their stone sizes.

Patients with stone size of 8 – 13 mm were 100 patients in each group and patients of stone size between 14 – 19 mm were 50 patients in each group.

Table-3: Showing stone size in both age groups

SIZE	***NO. OF PATIENTS***		***TOTAL***
	STENTED	***NON-STENTED***	
8 - 10mm	45	45	90 (30.0%)
11 - 13mm	55	55	110 (36.6%)
14 – 16mm	35	35	70 (23.3%)
17 - 19mm	15	15	30 (10.0%)

PRIMARY TREATMENT

In our study overall stone-free rate at three months was 90.6% (272/300). Clearance after first sitting was 56.3% (169/300), after second sitting was 29.0% (87/300) and after third sitting was 5.3% (16/300).

Table-5: Showing number of sittings in both age groups

NO. OF SITTINGS	***NO. OF PATIENTS***		***TOTAL***
	STENTED	***NON-STENTED***	
ONE	79 (52.6%)	90 (60.0%)	169 (56.3%)
TWO	41 (27.3%)	46 (30.6%)	87 (29.0%)
THREE	11 (7.3%)	5 (3.3%)	16 (5.3%)
TOTAL	131 (87.3%)	141 (94.0%)	272/300 (90.6%)

P= 0 .235 not significant

PRIMARY TREATMENT

The patients were categorized according to stone size and the number of sittings they under went in the table below.

Table-6: Showing number of sittings according to stone size in both age groups.

SIZE OF CALCULUS	***NO. OF PATIENTS***						***TOTAL***
	STENTED			***NON-STENTED***			
	1st sitting	***2^{nd} sitting***	***3^{rd} sitting***	***1st sitting***	***2^{nd} sitting***	***3^{rd} sitting***	
8-10mm	34	8	3	39	6	0	90/300
11-13mm	35	11	9	38	14	3	110/300
14-16mm	9	16	10	11	18	6	70/300
17-19mm	1	6	8	2	8	5	30/300
TOTAL	**79/150**	**41/150**	**30/150**	**90/150**	**46/150**	**14/150**	

I – SITTING P=0.963 not significant

II – SITTING P=0.858 not significant

III– SITTING P=0.540 not significant

PRIMARY TREATMENT

The patients who underwent three sittings of ESWL and became stone free were named as success and those who did not become stone free after three months and/or needed any other ancillary procedures were named as failure of ESWL. Of the stented group 11 patients were stone free and 19 patients failed to ESWL therapy. Where as in the non-stented group 5 patients had a successful ESWL therapy and 9 patients failed to ESWL.

Table- 7: Showing the success of rate after 3rd sitting of ESWL

SIZE OF CALCULUS	***NO. OF PATIENTS***			
	STENTED		***NON-STENTED***	
	SUCCESS	***FALIURE***	***SUCCESS***	***FALIURE***
8-10mm	1	2	0	0
11-13mm	2	7	1	2
14-16mm	4	6	2	4
17-19mm	4	4	2	3
TOTAL	11	19	5	9

STENTED - P=0.686 not significant

NON STENDED - P=0.969 not significant

STONE FREE RATE – SIZE

Clearance according to size: 8mm to 10mm were 97.7%, 11mm to 13mm were 91.8%, 14mm to 16mm were 85.7% and 17mm to 19mm were 76.6%. 9.3% patients did not have successful outcome. Of these, 7% cases had incomplete fragmentation and were termed as SWL failures. They required auxiliary procedures in the form of open ureterolithotomy for two cases and nineteen cases (6.3%) underwent ureteroscopy. The remaining seven cases had effective fragmentation but incomplete clearance and underwent URS with stone extraction for the same.

Table – 8: Stone free rate according to stone size

SIZE	***NO. OF PATIENTS***		***TOTAL***
	STENTED	***NON-STENTED***	
8-10mm	43/45 (95.5%)	45/45(100%)	88/90 (97.7%)
11-13mm	48/55 (87.2%)	53/55 (96.3%)	101/110 (91.8%)
14 – 16mm	29/35 (82.8%)	31/35 (88.5%)	60/70 (85.7%)
17 – 19mm	11/15 (73.3%)	12/15 (80%)	23/30(76.6%)
TOTAL	131/150 (87.3%)	141/150 (94%)	272/300 (90.6%)

P = 0.015, Significant

COMPLICATIONS

Post SWL complications consisted of 17 (5.6%) patients with hematuria, fever in 9 (3%) patients which was treated with culture specific antibiotics, steinstrasse in 17 (5.6%) patients and ureteric colic requiring hospital admissions 15 (5%) patients. All the colic patients had stone size larger than 13 mm.

Table- 9: Showing the complications in both age groups.

COMPLICATIONS	***NO. OF PATIENTS***		***TOTAL***
	STENTED	***NON-STENTED***	
HAMATURIA	14(9.3%)	3(2.0%)	17 (5.6%)
FEVER	7(4.6%)	2(1.3%)	9 (3.0%)
STIENSTRASSE	9 (6%)	8 (5.3%)	17 (5.6%)
URETERIC COLIC	1 (0.6%)	14 (9.3%)	15 (5%)

P=0.000 significant

COMPLICATIONS - LUTS

Among the lower urinary tract symptoms (LUTS), frequency was seen in 75 (25%) cases, urgency in 84 (28%) cases, dysuria in 109 (36%) cases and nocturia in 21 (7%) cases. Most of the lower urinary tract symptoms were seen in stented (group A) patients.

Table-10: Showing the incidence of LUTS in both age groups.

LUTS	***NO. OF PATIENTS***		***TOTAL***
	STENTED n = 150	***NON-STENTED n =150***	
FREQUENCY	64 (42.6%)	11 (7.3%)	75 (25%)
URGENCY	69 (46%)	15 (10%)	84 (28%)
DYSURIA	86 (57.3%)	23 (15.3%)	109 (36%)
NOCTURIA	17 (11.3%)	4 (2.6%)	21 (7.0%)

Since P=0, Frequency Vs stented with Non stented, Significant

Since P=0, Urgency Vs stented with Non stented, Significant

Since P=0, Dysuria Vs stented with Non stented, Significant

Since P=0.162, Nocturia Vs stented with Non stented, Not Significant

STATISTICAL ANALYSIS OF RESULTS

The SPSS Version 17 package was employed to find Pearson's chi-square test and Fisher's exact chi-square test for the statistical analysis.

Table 1 - Table 7, shows that there is no association between age group, sex, side and number of sittings in the success of ESWL among stented and non-stented patients, since P values are greater than 0.05.

Table 8, infer there is significant association in the stone free rate among stented and non-stented group since P values are less than 0.05.

Table 9-10, also shows that there is significant association in the complication (P=0.000) and LUTS (P=0) among stented and non-stented group of patients.

DISCUSSION

ESWL has revolutionized the treatment strategy of urolithiasis world wide and continue to be a major therapeutic modality for treating the majority of upper urinary tract stones. Its non invasive nature along with high efficacy has resulted in outstanding patient and surgeon acceptance.

ESWL and ureteroscopy used in the management of upper ureteric stones have valid advantages and disadvantages. Supporters of ESWL claim that it is effective and noninvasive, is associated with less morbidity, requires lesser anesthesia than ureteroscopy, and seldom requires ureteric stents. Critics argue that the success rates are not as high as those of ureteroscopy, equipment availability may be limited, visualization of the stone is often difficult, attainment of a stone-free state requires a longer time and follow-up, re-treatment rates are higher, and costs are higher. Supporters of ureteroscopy claim that it is highly successful and minimally invasive, is associated with minimal morbidity, can be used with larger and multiple stones, and has high immediate stone-free rates. Critics argue that it requires specialized training, requires more anaesthesia, and more often requires ureteric stent placement.

We had an overall stone-free rate of 90.6%. This result compares favorably with previously published series and is a timely reminder that good stone-free rates can be achieved without the use of ureteroscopy. Previous studies with different lithotriptors reported success rates between 80-90%.[36] In the study of Gnanapragasam et al.[37], stone-free rates for upper ureteric stones were 90%. Failure of ESWL was seen in patients with stone size >1.3 cm. Similarly, Mogensen and Anderson[38] reviewed outcomes of 199 patients with ureteric stones treated with SWL. Stone-free rates at three and six months after SWL for upper ureteric stones were 86% and 91% respectively.

Hofbauer et al.[39] evaluated the outcome of 1259 ureteric stones with success rate of upper ureteric stones being 98%. We had retreatment rate of 59% and auxiliary procedures were required in 8% cases. Fetner et al[40] found a statistically significant relation between stone size and success rate. The American Ureteral Stones Clinical Guidelines Panel reported that, for proximal ureteric stones, the success rate of SWL was 87% for <1 cm stone and 76% for >1 cm stone. In our study 95% success was seen in cases with <1 cm stone while 85% success was seen in >1 cm stone. This success rate may be due to better stone localization techniques and use of standard lithotripter (Dornier Delta II lithotripter).

Pushback technique was not used in any of our patients. All stones were treated without manipulating the position of the stone. There is no significant difference in success rates for in situ versus pushback ESWL. [41] Macroscopic expansion space is not required for successful fragmentation of ureteric calculi.[42] Ureteral manipulations using pushback technique are associated with 5.1% perforation rate. We also observed that the presence of DJ stents significantly reduces the success rates. DJ stents were inserted in 150 cases preoperatively of which eight (20%) patients required auxiliary procedure in the form of ureteroscopy. Ryan et al [43] showed that in situ ureteric stents impair ureteric peristalsis and trap large fragments thus delaying stone clearance. Presence of DJ stent next to the stone may prevent full impact of the shock wave on the stone. However, DJ stents are a must in stones causing severe obstruction or solitary functioning renal unit. [44]

Several authors have attempted to identify predictive factors associated with the failure of ESWL treatment for ureteric stones. Abdel-Khalek et al [45] in a study of 938 patients, defined a stone transverse diameter of > 10 mm, site of stone and presence of a stent as predictors of failure of ESWL. Kim et al [46] in a study of 369 patients investigating factors that influence fragmentation of ureteric stones, reported as such the size of stone, radio-opacity and degree of obstruction, but not the location. In a study by Pareek et al [47] identified increased body mass index (BMI) and a high Hounsfield units (HU) value as independent predictors of the results of ESWL for upper urinary tract stones, and devised an equation to compute the probability of treatment failure, which was $1/1 + 2.7(-z)$, where $Z = 0.294\ BMI + 0.13\ HU - 18.98$.

Ureteric stents are significant tools in the management of upper urinary tract conditions. In the context of stone disease, ureteric stents are usually inserted in cases of obstruction in a solitary kidney, patients with obstruction and fever at risk of sepsis, prolonged pain and to prevent deterioration of renal function. Furthermore, their use is common practice in cases where large stones (usually > 20 mm) are treated by ESWL, and for managing steinstrasse and/or obstruction after ESWL.

The possible effect of the presence of a stent in ESWL has been an issue of long-standing debate. Initially, it was thought that stents might contribute to successful stone passage. Bierkens et al [48] randomized 64 patients with large renal stones (but no ureteric stones) and found a difference in the stonefree rate in 3 months of 9% in favour of the stented population (44% vs 35%), while Pryor and Jenkins [49] found a difference of 18% in the stone-free rate in favour of the unstented patients with ureteric stones. Later studies of stents and ureteric stones suggested that they do not affect the final stone-free rate. Stents are associated with significant morbidity, including discomfort and irritative symptoms, and recent reports on the outcome of ESWL are contradictory. El-Assmy et al [50] randomized 186 patients with ureteric stones and moderate/severe hydronephrosis, and the results were better but not statistically significant for the unstented patients (91% vs 85% stone-free rate, $P = 0.25$), while Musa [51] in 120 patients with renal stones found a stone-free rate of 91% vs 88% in favour of the unstented population an also found there was slightly higher incidence of fever in stented patients. This could be explained by the fact that patients with DJ stent had two additional procedures performed and a foreign body was placed in a normally sterile system.

In a study by Khaled in the risk factors for the formation of a steinstrasse after extracorporeal shock wave lithotripsy, the overall incidence of steinstrasse was 3.97%.[52] Stone size and site, renal morphology and shock wave energy are the significant predictive factors controlling steinstrasse formation. If a patient has a high probability of steinstrasse formation, close followup with early intervention or prophylactic pre-ESWL ureteral stenting is indicated.

Multiple large series have shown overall stone-free rates of more than 80% when considering SWL for proximal ureteral stones. A series of 397 upper ureteral stones treated with a Modulith SL-20 lithotriptor. Of the stones treated 91% were 14 mm or less in diameter and the stone-free rate was 84.3% at 3-month followup. Stent-related symptoms have a high prevalence and may affect over 80% of patients. They include irritative voiding symptoms including frequency, urgency, dysuria, incomplete emptying; flank and suprapubic pain; incontinence, and hematuria. Assessment tools are important to determine their intensity and allow for comparisons between different points in the timeline. The Urinary Stent Symptom Questionnaire (USSQ) is the most proper tool used for this purpose. Management should be focused on the prevention and management of symptoms. In this sense, research has focused on new materials and stent designs that would be more compatible to the physiologic properties of the urinary tract and medications that can ameliorate the sensitivity and motor response of the bladder.[53]

Our results also show that the presence of a ureteric stent is associated with a higher failure rate of ESWL for ureteric stones. This might be for several reasons, such as difficulties in targeting, energy loss and the effect of the stent on peristaltic movements of the ureter, leading to reduced clearance of fragments. Ureteric stents should still be used in cases of sepsis, and in patients with deteriorating renal function due to obstruction or those with intolerable pain. However, the routine use of ureteric stents in patients offered ESWL for ureteric stones, irrespective of size or position in the ureter, should be considered with caution.

Although most SWL complications are minor and self-limiting, such as transient hematuria, pain, nausea and vomiting, there are also life threatening case reports described in the literature. In a study by Nazim Mohayuddin et al [54] the lower urinary tract symptoms e.g urinary frequency, nocturia, urgency, dysuria and haematuria were quite high in the stented group (45%, 12.5%, 47.5%, 57.5%, 92.5.%) as compared to the non – stented group (7.5%, 2.5%, 10%, 15%, 67.5%) respectively. This similar findings were noted in the other studies e.g Perminger et al [55] found a higher incidence of LUTS in patients with DJ stents than in the control group (43% vs 25%). Similarly in the study by Paramjit S [51] et al the incidence of frequency, urgency, dysuria was higher in the stented group. The same finding were reported by Musa who found a much higher frequency of lower urinary tract symptoms (85%) in the stented group as compared to the non stented group. It was suggested that the stent related LUTS were due to the presence of foreign body in the urinary bladder irritating the trigone and the bladder neck. Islam AG [56] in a study with 60 patients concluded that no significant difference statistical difference was oberseved in stone free rate between stented and non-stented groups, but patients in the stented group had significant side effects predominantly dysuria, urgency, frequency and suprapubic pain which was attributed to the stent.

In our study, the stented group of patients had more lower urinary tract symptoms than the non – stented group of patients.

CONCLUSION

1) Treatment with ESWL has a low morbidity and high effectiveness.

2) Pre ESWL ureteral stenting provides no additional benefit over in situ ESWL.

3) Uretral stents are associated with significant patient discomfort and morbidity.

4) Although ureteral stents are associated with more irritative symptoms, their use resulted in fewer hospital readmissions compared to when no stent was used to treat upper ureteric calculus.

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MASTER CHART

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
1	42/F	LT	8 x7	Done	1		D
2	32/F	RT	9x11	Not done	1		F,U
3	39/M	RT	16x11	Done	1		F,U,D
4	60/M	RT	19x17	Not done	3		
5	26/M	LT	12x11	Done	1		
6	54/F	LT	12x11	Not done	1		
7	40/F	RT	10x9	Done	2		F,U,D,N
8	60/M	RT	15x10	Not done	1		F,U,D,N
9	21/M	LT	8x7	Not done	1		
10	60/F	RT	10x8	Done	3	URS&ICL	U,D
11	34/M	LT	9x8	Done	1		D,N
12	47/M	LT	10x9	Not done	1		
13	45/M	RT	9x11	Not done	1		
14	28/F	LT	14x15	Done	3		
15	30/F	RT	11x9	Done	1		D
16	65/M	RT	10x11	Done	1		F,U,D
17	27/M	RT	9x8	Done	1		F,U,D
18	40/M	RT	8x11	Done	1		D
19	45/F	LT	9x8	Not done	1		
20	39/F	LT	9x8	Done	1		D
21	55/M	LT	11x12	Not done	2		F,U,D
22	35/M	RT	8x5	Done	1		D
23	18/F	RT	8x5	Done	1		
24	51/M	LT	11x10	Done	3	URS&ICL	F,U,D,N
25	25/M	LT	9 X8	Done	2		D
26	40/M	LT	8 x7 mm	Not done	1		
27	23/M	LT	8 X 9	Not done	1		
28	30/M	RT	19 X 18	Done	3	URS&ICL	D
29	60/M	LT	10 X 9	Done	1		U,D
30	24/M	LT	9 X 8	Not done	1		
31	40/M	RT	9 X8	Done	1		
32	34/M	LT	8 X9	Not done	2		
33	35/M	LT	11 X13	Done	3	URS&ICL	F,U,D
34	52/M	LT	1X0.9	Not done	1		
35	40/M	RT	9 X8	Done	1		F,U,D
36	44/M	RT	11 X10	Not done	1		D
37	33/M	RT	11 X9	Not done	3		
38	38/F	LT	8 X9	Done	1		D,N
39	62/M	RT	14 X 11	Not done	2		F,U,D
40	42/M	LT	11 X 9	Not done	1		
41	51/F	LT	11 X10	Done	3		
42	34/M	RT	10 X9	Done	2		D
43	25/F	LT	9 X8	Not done	1		
44	34/F	LT	9 X10	Done	1		F,U,D
45	62/M	LT	10 X11	Done	1		F,U,D
46	29/M	RT	11 X13	Done	3		
47	30/M	RT	8 X 9	Not done	1		
48	52/M	RT	11 X13	Done	2		F,U,D
49	30/M	RT	11 X 13	Not done	1		
50	24/M	LT	8 X 9	Done	1		

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
51	38/M	LT	16 X13	Done	2		D
52	20/M	LT	15 X12	Not done	3	URS&ICL	F,U,D,N
53	52/M	LT	8X 9	Not done	1		
54	32/M	RT	14 X11	Not done	3		F,U,D
55	77/M	RT	13 X11	Not done	1		
56	35/M	RT	13 X11	Done	2		F,U,D
57	40/M	RT	14 X 10	Not done	1		D
58	53/M	RT	8 X9	Not done	1		
59	45/M	LT	15 X11	Not done	2		F,U,D,N
60	59/M	RT	16 X10	Done	3		U,D
61	43/M	LT	8 X9	Done	1		
62	41/F	LT	8X9	Not done	1		
63	31/M	LT	10 X9	Done	1		
64	36/F	RT	11 X10	Done	1		F,U,D
65	29/F	RT	10X12	Done	1		D
66	28/M	LT	8 X9	Not done	1		
67	35/F	RT	10 X9	Not done	1		
68	58/M	LT	11X13	Done	1		F,U,D
69	23/F	RT	8 X9	Done	3		
70	40/M	RT	11X 10	Done	1		F,U,D
71	47/F	LT	8 X9	Not done	1		
72	45/M	RT	11X10	Not done	1		
73	56/M	LT	12 X13	Done	1		F,U,D
74	32/M	RT	12 X11	Not done	1		D
75	33/M	LT	8X9	Not done	1		
76	40/M	LT	8X 9	Done	1		F,U,D
77	23/F	LT	10 X11	Not done	1		
78	38/M	LT	15 X11	Not done	3	URS&ICL	F,U,D
79	35/F	LT	17 X12	Not done	1		
80	43/M	LT	11 X9	Done	2		
81	34/M	LT	11X9	Done	1		F,U,D
82	37/M	LT	8X9	Not done	1		
83	28/M	LT	12 X11	Done	1		
84	37/M	LT	10 X11	Not done	1		
85	50/F	RT	11X10	Not done	1		
86	39/M	RT	8 X9	Done	1		F,U,D
87	33/F	LT	10 X9	Done	3		
88	25/M	RT	15 X14	Done	1		F,U,D
89	50/F	LT	11 X10	Not done	1		
90	42/M	LT	12 X10	Not done	2		
91	39/M	RT	8 X9	Done	1		F,U,D,N
92	29/F	RT	11 X10	Done	1		
93	27/F	RT	8 X9	Not done	1		
94	24/F	RT	8 X9	Done	1		
95	45/M	RT	15 X10	Not done	2		F,U,D
96	27/M	RT	12X9	Done	1		F,U,D
97	33/M	RT	8X9	Not done	1		
98	38/M	RT	17 X13	Done	3	URS&ICL	F,U,D
99	25/M	RT	15 X9	Not done	2		
100	37/F	RT	17 X10	Not done	2		
101	38/M	RT	8 X9	Done	1		
102	39 / M	LT	12 X10	Done	1		F,U,D

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
103	52/M	RT	14x13	Not done	2		
104	34/M	LT	11x10	Done	1		
105	41/M	LT	11x9	Not done	1		
106	38/M	RT	14x11	Done	2		F,U,D
107	57/M	RT	16x15	Done	3		D
108	45/F	LT	13x11	Not done	3	URS&ICL	
109	30/M	LT	12x9	Not done	2		
110	39/M	LT	12x9	Done	1		
111	29/M	RT	12x11	Done	1		F,U,D
112	33/M	LT	13x11	Done	2		
113	40/M	LT	11.x10	Not done	1		
114	45/M	RT	11.x 9	Not done	1		
115	36/F	RT	9x8	Done	1		
116	60/M	RT	13x11	Not done	1		
117	28/M	LT	10x9	Done	1		F,U,D
118	30/M	LT	11x9	Not done	1		
119	26/M	LT	10x9	Done	3		
120	40/F	LT	9x8	Not done	1		D
121	41/M	LT	10x9	Done	1		
122	37/F	LT	11x10	Not done	1		
123	30/M	RT	10x11	Done	1		D
124	40/M	LT	11x10	Not done	2		
125	27/M	LT	9x8	Not done	1		
126	50/F	LT	9x8	Not done	1		
127	30/M	LT	10x9	Done	1		
128	50/M	RT	11x10	Not done	1		
129	45/M	RT	18x12	Not done	2		D,N
130	24/M	LT	8x12	Done	1		F,U,D
131	35/M	LT	11x10	Not done	1		
132	24/F	RT	14x11	Done	1		D,N
133	20/M	LT	11x10	Not done	1		
134	38/F	RT	13x11	Not done	3		
135	42/F	LT	12x10	Not done	1		
136	28/F	LT	12x11	Not done	1		D
137	55/M	LT	11x10	Done	1		
138	55/M	LT	12x10	Done	1		F,U,D
139	60/F	LT	13x12	Done	3		D
140	60/M	LT	12x11	Not done	1		
141	23/F	RT	8x9	Done	1		
142	32/M	RT	11x10	Not done	1		
143	33/M	RT	11x10	Not done	1		
144	27/M	RT	15x13	Done	2		F,U,D
145	30/M	LT	13X11	Not done	1		
146	23/M	RT	8x9	Not done	1		
147	27/F	LT	10x9	Done	1		D
148	50/M	LT	11x10	Not done	2		
149	42/M	LT	11x10	Done	1		F,U,D
150	26/M	LT	10x9	Not done	1		
151	33/M	LT	12x10	Done	1		
152	31/M	RT	8x9	Done	1		
153	47/M	RT	13x11	Not done	1		
154	23/M	RT	10x9	Done	3		

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
155	30/M	LT	11x10	Not done	1		
156	40/M	RT	11x10	Not done	1		
157	39/F	LT	14x13	Not done	2		D
158	38/M	LT	11x8	Done	1		
159	42/F	LT	16x13	Not done	3	URS&ICL	F,U,D
160	39/M	RT	15x11	Not done	1		F,U,D,N
161	30/M	RT	12x11	Done	1		D
162	38/M	LT	12x11	Done	1		
163	49/M	LT	12x11	Done	2		
164	26/M	RT	11x10	Not done	1		
165	52/M	LT	12x11	Done	1		U,D
166	30/M	RT	10x8	Done	1		
167	35/M	RT	8x7	Not done	2		
168	42/M	LT	10x.8	Not done	1		
169	31/M	RT	8x7	Done	1		
170	34/M	RT	8x7	Not done	1		
171	35/M	LT	12x11	Done	1		
172	36/F	LT	18x16	Not done	3	URS&ICL	D
173	31/M	LT	9x8	Not done	1		
174	30/M	LT	11x10	Done	2		
175	27/M	RT	12X11	Done	1		D
176	31/M	RT	12x11	Not done	1		
177	47/M	LT	9x8	Not done	2		
178	50/F	LT	10x9	Done	1		
179	27/M	RT	15x13	Done	3		F,U,D
180	39/M	LT	16x13	Not done	3		
181	46/F	RT	14x12	Done	1		
182	53/F	RT	12x11	Not done	1		
183	19/M	RT	10x8	Done	3		
184	50/M	RT	11X10	Not done	1		
185	28/M	LT	14x12	Done	2		F,U,D,N
186	42/M	LT	14x12	Not done	1		
187	29/M	RT	13x12	Not done	1		F,U,D,N
188	32/M	RT	17x12	Done	2		D
189	37/M	LT	14x11	Done	2		F,U,D
190	35/F	LT	11x8	Not done	1		
191	54/M	RT	11x10	Done	1		F,U,D
192	27/M	LT	13x10	Not done	2		
193	40/M	LT	11x10	Done	1		
194	36/M	LT	16x15	Not done	3		
195	63/M	RT	9x.8	Done	1		
196	48/M	LT	11x10	Not done	1		
197	36/M	LT	13X11	Not done	2		
198	33/M	LT	11x.0	Not done	1		
199	22/F	LT	10x9	Not done	1		
200	37/M	LT	12x10	Done	1		F,U,D
201	34/M	LT	9x8	Not done	2		
202	34/M	RT	14x13	Not done	1		
203	40/F	LT	15x9	Done	2		F,U,D,N
204	60/M	LT	9X.8	Not done	1		
205	60/M	RT	10x9	Not done	1		
206	26/M	RT	13x.1	Done	1		F,U,D

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
207	60/M	RT	10x8	Not done	1		
208	30/F	RT	11x12	Not done	2		
209	41/M	LT	11x10	Not done	1		
210	35/F	RT	11x1.0	Done	1		F,U,D
211	46/M	LT	13x12	Done	1		D
212	28/M	LT	9x8	Not done	1		
213	46/M	LT	14x13	Not done	2		
214	39/M	LT	12x10	Done	1		F,U,D,N
215	36/F	LT	10x8	Not done	1		
216	53/M	LT	9x8	Not done	1		
217	45/M	LT	18x15	Done	2		F,U,D
218	69/M	LT	18x16	Done	3	URS&ICL	F,U,D
219	29/M	LT	10x8	Not done	1		
220	38/M	LT	12x11	Done	2		
221	24/M	LT	11x10	Not done	1		D
222	40/M	RT	10x8	Not done	1		
223	25/M	LT	9x8	Not done	1		
224	27/M	RT	10x8	Done	1		F,U,D
225	34/F	RT	7x6	Done	1		F,U,D
226	37/M	LT	11x10	Not done	1		
227	21/M	RT	11x10	Not done	1		
228	45/M	LT	12x11	Not done	1		
229	40/M	RT	15x11	Done	2		F,U,D,N
230	40/F	RT	16x14	Not done	2		F,U,D,N
231	4/M	RT	16x13	Done	2		
232	28/M	LT	13x11	Not done	1		F,U,D
233	28/M	LT	13x11	Not done	1		
234	40/M	RT	15x9	Done	3	URS&ICL	F,U,D
235	22/M	LT	12x8	Not done	1		
236	16/M	LT	10x6	Done	1		U,D
237	32/M	LT	10x8	Not done	1		
238	50/F	LT	13x10	Not done	1		F,U,D
239	40/F	RT	11x10	Done	1		F,U,D
240	41/M	RT	13x12	Not done	1		
241	25/M	RT	13x11	Done	1		
242	67/M	LT	11x12	Done	1		
243	23/M	RT	14x11	Not done	2		
244	62/M	RT	11x.0	Done	1		F,U,D
245	55/M	RT	13x12	Done	1		
246	56/M	RT	16x15	Not done	3	URS&ICL	F,U,D
247	52/F	LT	11x10	Not done	1		
248	32/M	LT	15x14	Done	2		F,U,D
249	29/F	RT	13x11	Done	1		
250	35/M	LT	11x10	Not done	1		
251	30/M	LT	10x9	Not done	1		
252	57/M	RT	.8x7	Done	1		F,U,D
253	18/M	LT	8x7	Done	1		U,D,N
254	26/M	LT	15x13	Not done	2		D
255	38/M	RT	15x13	Not done	3	URS&ICL	
256	25/M	RT	9x7	Done	1		F,U,D
257	57/M	RT	15x14	Not done	1		
258	32/M	LT	11x9	Not done	1		

S.No	Age/Sex	Side	Size mm	Stenting	No. of Sittings	Sec. Proce	LUTS
259	54/F	LT	11x10	Done	1		
260	25/M	RT	12x10	Not done	1		
261	37/M	RT	14x11	Not done	2		
262	32/M	RT	14x11	Done	3	URS&ICL	F,U,D
263	54/M	LT	13x11	Not done	1		
264	60/M	RT	17x16	Not done	2		
265	28/M	LT	13x10	Not done	1		
266	38/F	LT	11x10	Done	1		F,U,D
267	19/M	RT	11x10	Not done	1		
268	39/M	LT	15x14	Not done	3	URS&ICL	
269	60/M	LT	10X9	Done	1		
270	35/M	LT	15x13	Not done	2		
271	25/M	RT	8x7	Not done	1		
272	23/M	LT	8x6	Done	1		F,U,D
273	32/M	LT	9X8	Not done	1		
274	31/M	LT	16x15	Done	2		
275	37/M	LT	16x15	Done	1		
276	26/M	LT	11x10	Not done	1		
277	29/M	RT	15x14	Done	3		F,U,D,N
278	45/F	LT	11x10	Done	1		F,U,D
279	67/M	LT	13x12	Done	1		F,U,D
280	28/M	RT	11x11	Not done	1		
281	50/M	RT	17x10	Done	3		
282	33/F	RT	9x8	Not done	1		
283	29/M	LT	9x7	Not done	1		
284	30/M	RT	13x12	Done	1		U,D
285	68/M	LT	11x9	Done	1		F,U,D
286	26/M	RT	8x7	Done	1		
287	25/M	RT	11.x12	Not done	1		
288	30/M	LT	10x9	Done	1		
289	39/M	LT	11x10	Not done	1		
290	25/M	RT	16x15	Done	3		U,D,N
291	38/M	LT	11x10	Not done	1		
292	65/M	LT	14x13	Not done	2		F,U,D
293	28/M	RT	10x9	Not done	1		
294	23/M	RT	11x.0	Done	1		F,U,D,N
295	79/M	LT	11x10	Done	1		
296	36/F	RT	11x10	Done	1		F,U,D
297	27/M	LT	13x11	Not done	2		
298	40M	RT	8x9	Done	1		F,U,D
299	47/M	RT	10X.9	Not done	1		
300	30/M	LT	11x10	Not done	1		

F -Frequecy, U - Urgency, D - Dysuria, N - Nocturia
H - Haematuria, F - Fever, S -Stienstrasse, UC - Ureteric Colic

Complications
H,F,S
S, UC
H,S, UC
S
H
H,F
S,UC

Complications
S
UC
UC
S,UC
F
F
H,F
H
UC
H,F
S
H,F,UC
S, UC
H

Complications
S
H
H
H

Complications
H
H,UC
H
F
H
S,UC
UC
H

Complications
UC
H
S
H
H

Complications
F
F,S
F
UC
S,UC

CHART 1-AGE DISTRIBUTION AMONG STENTED GROUP

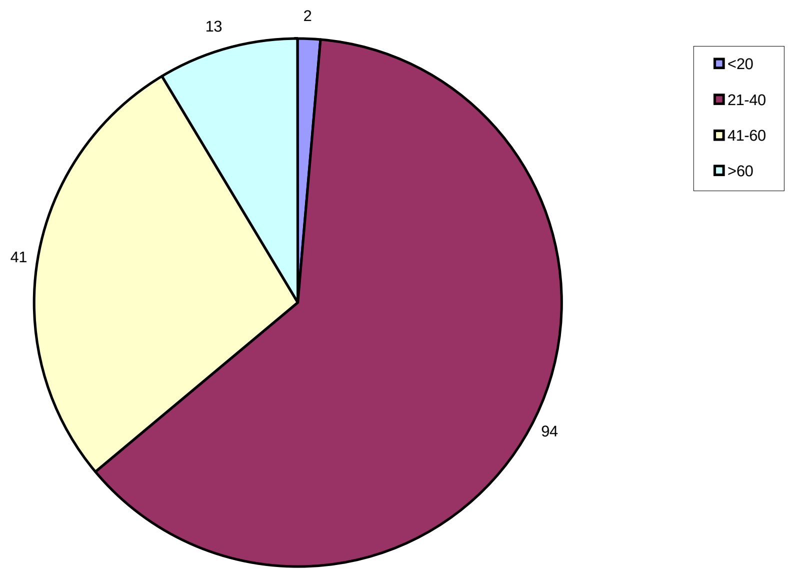


CHART 2-AGE DISTRIBUTION AMONG NON STENTED GROUP

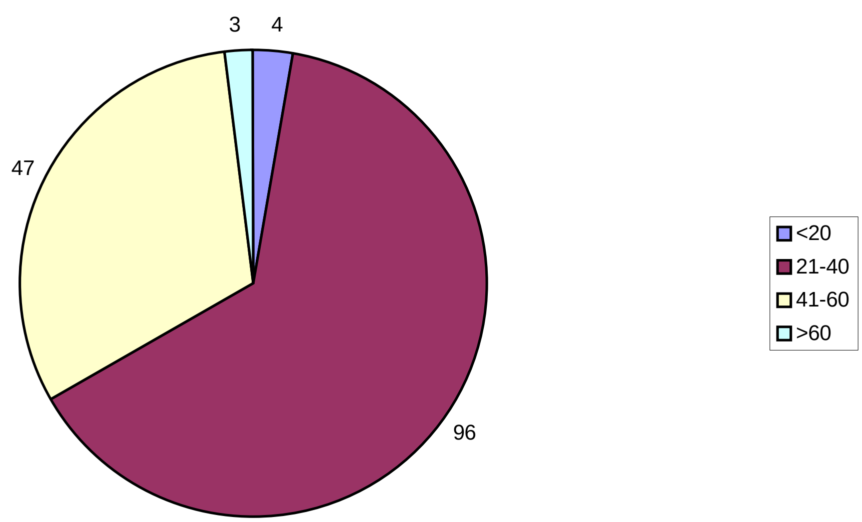


CHART 3 -STONE FREE RATE ACCORDING TO SIZE AMONG STENTED AND NON STENTED

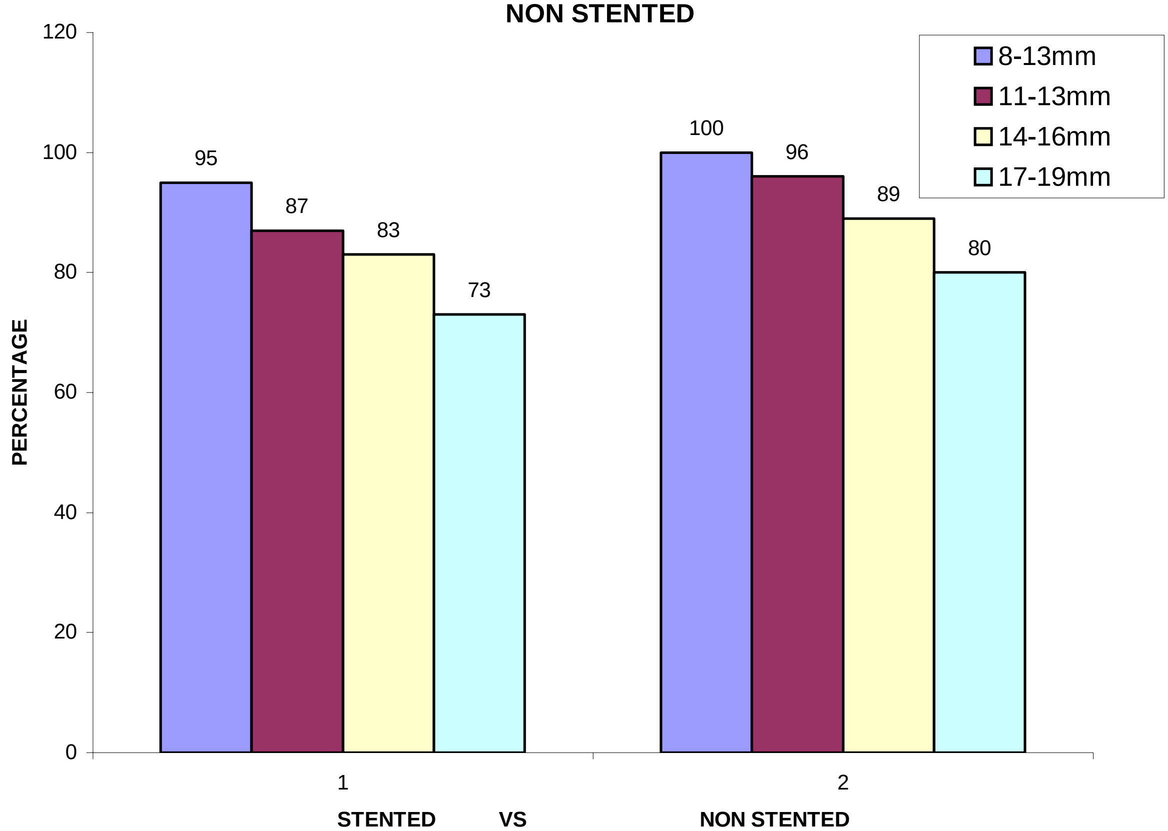
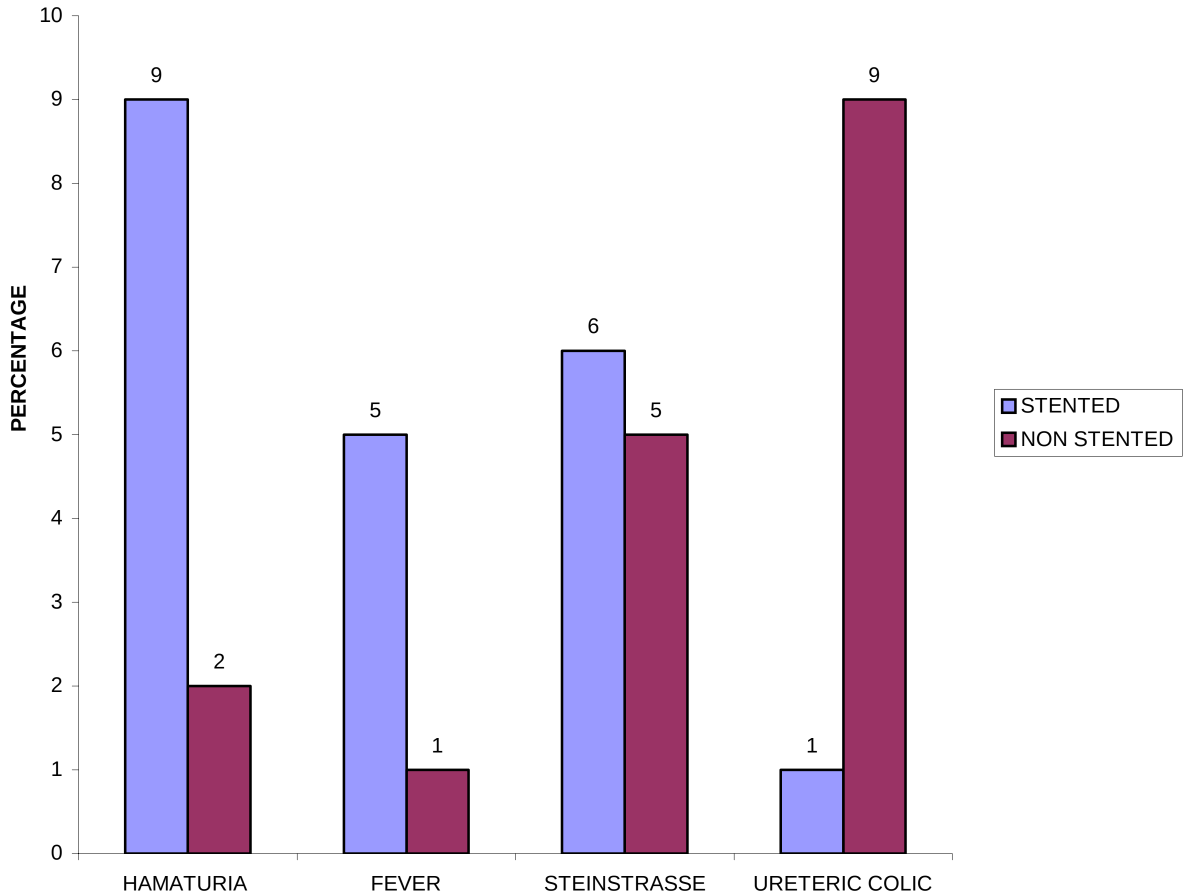


CHART 4- PERCENTAGE OF COMPLICATIONS AMONG STENTED AND STENTED

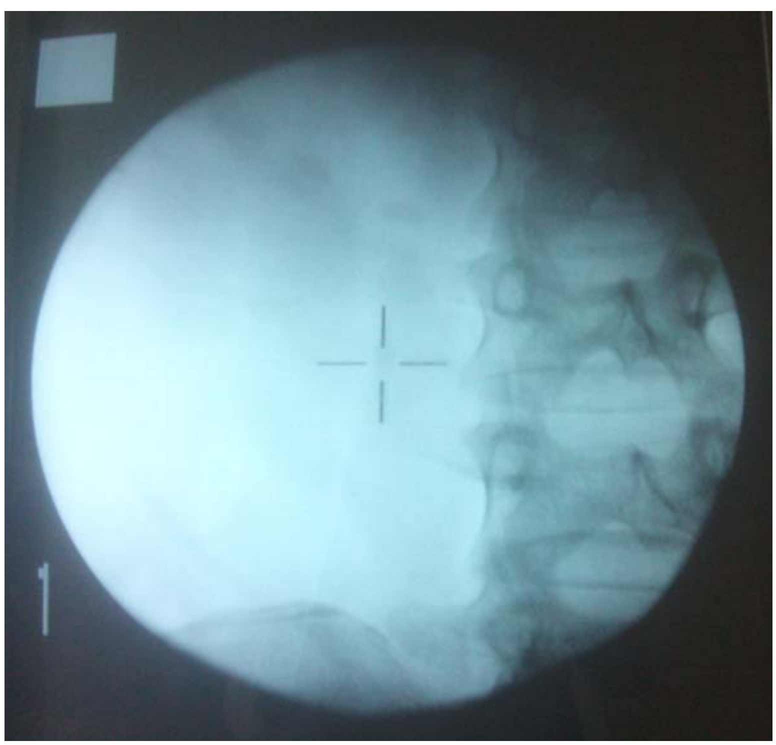


<u>PLAIN X-RAY KUB WITH UPPER URETERIC CALCULUS WITHOUT DJ STENT</u>

<u>PLAIN X-RAY KUB WITH UPPER URETERIC CALCULUS WITH DJ STENT</u>

CT SCAN WITH UPPER URETERIC CALCULUS

FLUROSCOPIC FOCUSING THE UPPER URETERIC CALCULUS



A COMPARATIVE ANALYSIS BETWEEN STENTED AND NON-STENTED TECHNIQUES IN EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY FOR UPPER URETERAL STONES

PROFORMA

NAME : **AGE & SEX :**

MRD NO :

ADDRESS :

PHONE NO:

HISTORY

PAIN – SITE , CHARACTER ,DURATION

HEMATURIA / PYURIA / DYSURIA

FEVER / VOMITING

OTHER LUTS

DM/HT/PT/IHD

H/O DRUG INTAKE

PREVIOUS INTERVENTION/ SURGERY

EXAMINATION

ABDOMEN :

GENITALIA / P.V :

P.R :

OTHER SYSTEMS :

INVESTIGATIONS

H.B% :
PCV% :
TC :
DC :
ESR :
URINE :ALB :
SUG :
DEP :

URINE C/S :

BLOOD SUGAR :
R.F.T: Bl.UREA :
Sr.CREATININE :
Sr.ELECTROLYTES:

X RAY KUB: RT/LT /SIZE
STENTED / NON-STENTED

U/S KUB: HUN / SIZE

IVU

C.T KUB

OTHER INVESTIGATIONS

ESWL - DETAILS

FOLLOW UP

TWO WEEKS:

X RAY KUB:

U/S KUB:

FIRST MONTH:

X RAY KUB:

U/S KUB:

SECOND MONTH:

X RAY KUB:

U/S KUB:

THIRD MONTH:

X RAY KUB:

U/S KUB:

RESULT:

SUCCESSFUL / FAILURE

REMARKS :

PATIENT CONSENT FORM

Study Details : A Comparative Analysis between Stented and Non-Stented Techniques in Extracorporeal Shock Wave Lithotripsy for Upper Ureteral Stones

Study Centre : Department of Urology, Madras Medical College, Chennai-600 003.

Patient may check (✓) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if) suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

I hereby consent to participate in this study. ☐

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests. ☐

Signature/ Thumb Impression:

Patient Name and Address: Place Date

Signature of Investigator

Study Investigator's Name: Place Date

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

"சிறுநீரக அதிர்வு அலைசிகிச்சை மூலம் சிறுநீரக குழாயின் மேல்பகுதியில் ஏற்பட்டுள்ள கல்லை உடைக்கும் சிகிச்சையின் திறனை அறிதல்"

ஆராய்சி நிலையம் : சிறுநீரக அறுவைசிகிச்சைப் பிரிவு,
சென்னை மருத்துவக்கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்கு பெறுவர் இதனை (✓) குறிக்கவும்.

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தகமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ பயன்படுத்திக்கொள்ள மறுக்கமாட்டேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் .... இடம் .... தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் ....

ஆய்வாளரின் கையொப்பம் .... இடம் .... தேதி

ஆய்வாளரின் பெயர் ....

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No: 04425305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.T.R. Ghurunaath
PG in MCh Urology
Madras Medical College, Chennai -3

Dear Dr. T.r. Ghurunaath

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the project / proposal / clinical trail entitled " A comparative analysis between stented and non- stented techniques in extracorporeal shock wave lithotripsy for upper ureteral stones 'No. 05102010.

The following members of Ethics Committee were present in the meeting held on 22.10.2010 conducted at Madras Medical College, Chennai -3.

1. Prof. S.K. Rajan, MD -- Chairperson
2. Prof. J. Mohanasundaram, MD,Ph.D,DNB -- Deputy Chairman
   Dean, Madras Medical College, Chennai -3
3. Prof. A. Sundaram, MD -- Member Secretary
   Vice Principal , MMC, Chennai -3
4. Prof R. Nandhini, MD -- Member
   Director, Institute of Pharmacology, MMC, Ch-3
5. Prof. Pregna B. Dolia , MD -- Member
   Director, Institute of Biochemistry, MMC, Ch-3
6. Prof. C. Rajendran , MD -- Member
   Director, Institute of Internal Medicine, MMC, Ch-3
7. Prof. Md. Ali, MD, DM -- Member
   Professor & Head ,,Dept. of MGE, MMC, Ch-3
8. Thiru. S. Govindasamy BA.BL -- Lawyer
9. Tmt. Arnold Soulina -- Social Scientist

We approve the Proposal to be conducted in its presented form.

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee